



The US Healthcare System: Unavoidable Realities, Harsh Truths and Stark Choices

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What's next?

OPTIMISM IN TIMES OF UNCERTAINTY

INTERNAL OPERATIONS CONFERENCE

JULY 19-22 2009



Keynote address: Laguna Niguel, 20 July 2009



A Few Current Challenges for the US Healthcare System

- \$2.4 trillion dollar expenditures (2008):
 16% of GDP (\$1 in every \$7)
- escalating and unsustainable fraction of GDP
- highest per capita expenditure in OECD
- \$510 billion cost of chronic disease
- 2 million annual hospital-acquired infections
- 2.5 million hospitalizations due to adverse Rx reactions
- highly variable treatment patterns
- slow diffusion of best practices

US Government Healthcare Expenditures (2007)*

- 28% total revenues
- Medicare = 13% Federal budget = 20% US healthcare expenditures
- Medicaid = approx 22% of state expenditures
 - versus 21% for K-12, 10% for higher education, 8% transportation
 - increased from \$89 billion in 2000 to \$151 billion in 2007
- Medicare Trustees project Hospital Insurance Trust Fund will be exhausted in 2019

* From: M. Hartman et. al. (2009) Health Affairs 28,246

Market Distortions and Perverse Incentives in Healthcare Delivery

- focus on late-stage detection and intervention
 - high cost
 - low reversibility of chronic disease processes
- multiple reimbursements for fragmented (siloed)
 care versus integrated management of patient needs
- illness versus wellness
- inadequate social and economic incentives for wellness

Fee-for-Service and Runaway Healthcare Costs

- the invisible hand of Adam Smith is absent from healthcare
- terminal illness for governments, business and patients/consumers
- supply creates its own demand
- caregivers make more money by providing more care
- consumers don't select treatment choice
- caregivers don't consider cost in treatment decisions
- neither consumers nor caregivers evaluate cost or benefit and simply seek "maximum" care

U.S. Healthcare Costs are Unevenly Distributed

- 0.5% patients consume 25% of healthcare budget
- 1% consume 35%
- 5% consume 60%
- 10% consume 70%
- 75% of cost is for patients with chronic diseases
- end-of-life care

Source: Healthcare Reform Now G. Halvorson, Chairman and CEO Kaiser Foundation Health Plan and Hospitals Wiley, NY 2007 p.2

Five Chronic Diseases Impose the Highest Cost in Healthcare Expenditures

- diabetes
- CAD
- CHF/COPD
- asthma
- depression
- cancer = 8%
- infectious diseases = 7%
- trauma = 6%
- ob/gyn. = 4%
- bone and joint care = 2%

70% total healthcare costs

Demographic Trends and the Clinical and Economic Burden of Complex, Chronic Conditions/Co-Morbidities



- 23% Medicare beneficiaries have 5 or more conditions
- polypharmacy and AEs
- poor patient compliance
- multiple physician/venue encounters
- poor communication/ coordination between siloed healthcare services
- procedure-based reimbursement versus care continuum integrated

Swine Flu ("Hamageddon?)



The Strategic Future of Healthcare

Economic Unsustainability

Reform and Rational Care

Confronting the Imbalance Between Infinite Demand and Finite Resources

Reasonable Expectations for Rational Healthcare

- what works
- why it works
- who it works for
- what works best
- when should it be used optimally

- validated evidence
- mechanism of action
- personalized medicine
- comparative effectiveness
- best practice guidelines, standard-of-care and malpractice

VALUE



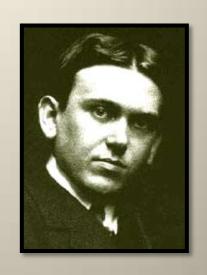


Mencken's First Law

"For every complex problem,
there is always a simple solution
and it is almost always dead wrong"

H.L. Mencken

Mencken's (Second) Law



 "Whenever they tell you it's not about the money.....it's about the money."

Complex and Pervasive Problems in Healthcare with No Easy Solutions

- different 'value' metrics for different constituencies
 - patients, physicians, payors, politicians
- public expectations and populist politics
 - zero-cost, zero-risk = zero care
- lack of transparency in costs, billing and reimbursement
- anachronistic institutional mechanisms for national health policy debate

CHANGING MINDS AND CHANGING BEHAVIORS

OMB on Four Pillars of US Health Reform



- health information technology
- comparative effectiveness research
- prevention and wellness efforts
- financial incentives to provide better care and reduce unnecessary or excessive care



Peter Orszag, Director, OMB Remarks at Institute of Medicine Workshop Washington, DC, 21 May 2009 Quoted in "The Gray Sheet" 25 May 2009 "We cannot, in a responsible sustainable way, go to universal coverage unless we're going to take cost control seriously"

"I go where the money is. Most of the increase in health spending comes from volume, not price, so that's the appropriate target. By and large affecting price will have a relatively small effect"



Dr. Ezekiel Emanuel
Senior Advisor, OMB
Presented at ASCO 30 May 2009
Cited in the Pink Sheet, 8 June 2009, p.7.

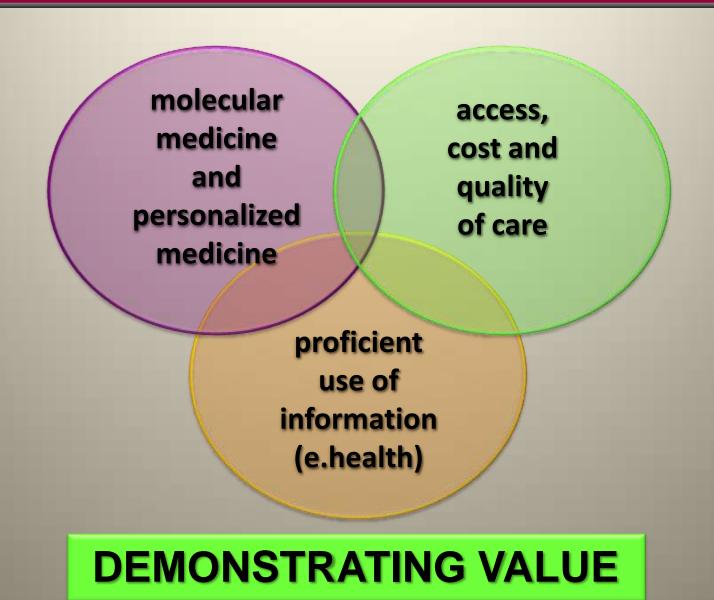
Defining New Value Propositions for Healthcare Delivery

- social and economic value of reducing disease burden will rise
 - earlier disease detection and mitigation
 - rational Rx and guaranteed outcomes
 - integrated care management of complex chronic diseases
 - extension of working life

Defining New Value Propositions for Healthcare Delivery

- prospering in an environment of increasing constraints
- managing the limit(s) of society's willingness and ability to pay for innovation
- controlling costs while enhancing quality and outcomes
- building new alliances to optimize value-driven outcomes
 - integration of Dx, Rx, Ix
- reliable information drives rational decisions

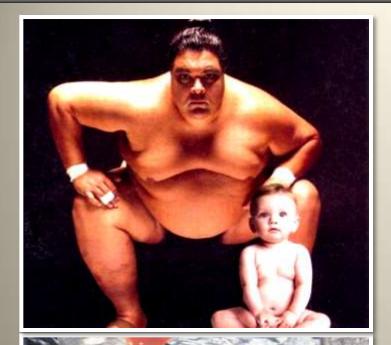
The Three Forces Shaping the Evolution of Healthcare





"Fortunately, treatment will be relatively inexpensive, since you have the generic form of the disease."

Ignoring The Obvious in Clinical Practice



- diseases are not uniform
- patients are not uniform
- a "one-size fits all" Rx approach cannot continue



- inefficiency and waste of empirical Rx
- cost of futile therapy
- medical error and AEs

Rational Therapeutics and Personalized medicine: Key Drivers



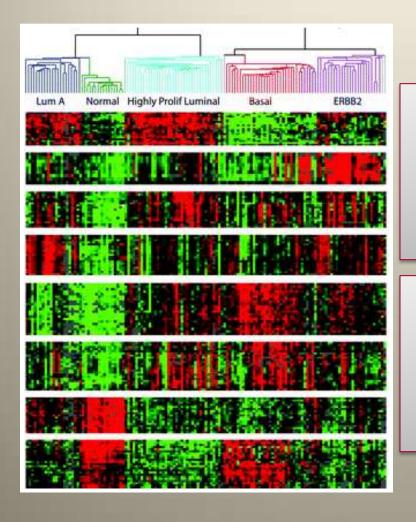


Science

Policy

Cost and Outcomes

Targeted Therapeutics: Identification of Subtypes of Disease with Different Molecular Pathologies



right Rx for right disease subtype

Dx – Rx combinations

K-RAS Profiling and Anti-EGFR Monoclonal Antibody Therapy









 higher response in patients with K-RAS versus mutant-K-RAS

estimated \$604 million/year savings (ASCO)

clinical guidelines



regulatory inertia



regulatory

demand





payor adoption

The Emergence of Drug: Diagnostic Combinations















Invader® chemistry

THIRD WAVE TECHNOLOGIES





















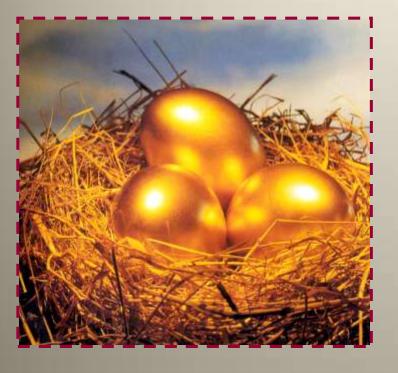


Personalized Medicine The Initial Era: Targeted Rx

- opening era in linking disease molecular pathology to rational Rx
- increasing payor, regulatory and public pressures for reliable ID of Rx-responsive patients
- demand for Dx-Rx combinations will intensify
- Dx-Rx combination will become an obligate element of NDA/BLA submission and product labeling
- development of Dx-Rx combinations as intrinsic components of R&D programs for investigational Rx

Molecular Diagnostics, Disease Subtyping and Pharmacogenomics

"Riches in the Niches"



- right diagnosis, the first time
- right Rx selection, the first time
- rise of Dx-Rx combination
- Rx approval and labeling/reimbursement only with obligate Dx?

Outcomes-Based Risk-Sharing Agreements (OBRAs)

UK: National Health Service

full or partial refund for non-responders







- four Rx cycles
- 50% reduction in serum M protein
- NHS continues to fund
- <50% response company refunds cost of Rx

Outcomes-Based Risk-Sharing Agreements (ORBAs) Come to the USA













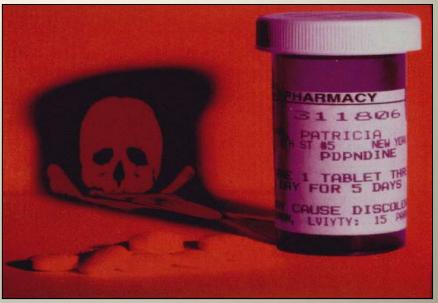




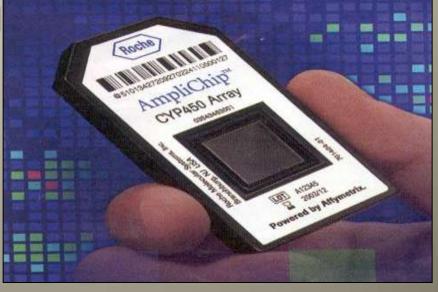
- reimburse average treatment cost (not just Rx) for fractures incurred after 6 months therapy
- improved Hb1Ac levels in diabetics over one year increases Rx discount to Cigna

Pharmacogenetic Predisposition to Adverse Drug Reactions





- 1.5 to 3 million annual hospitalizations (US)
- 80 to 140 thousand annual deaths (US)
- est. cost of \$30-50 billion





Alert 7/24/08

 update labeling for Abacavir (Ziagen) to require pre-therapy screening for HLA-B*5701 allele to avoid fatal hypersensitivity



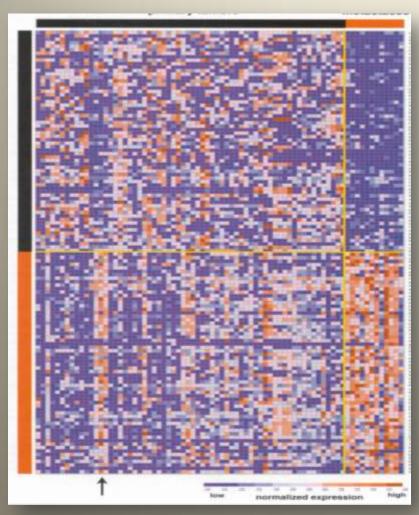


Table of Valid Genomic Biomarkers in the Context of Approved Drug Labels

http://www.fda.gov/cder/genomics/genomic_biomarkers_table.htm

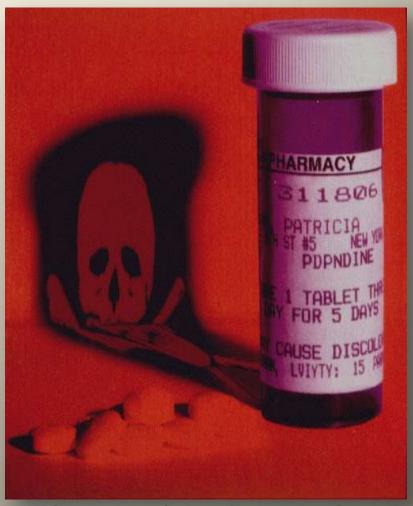
From Pharmaceuticals to Pharmasuitables

Disease Subtyping:



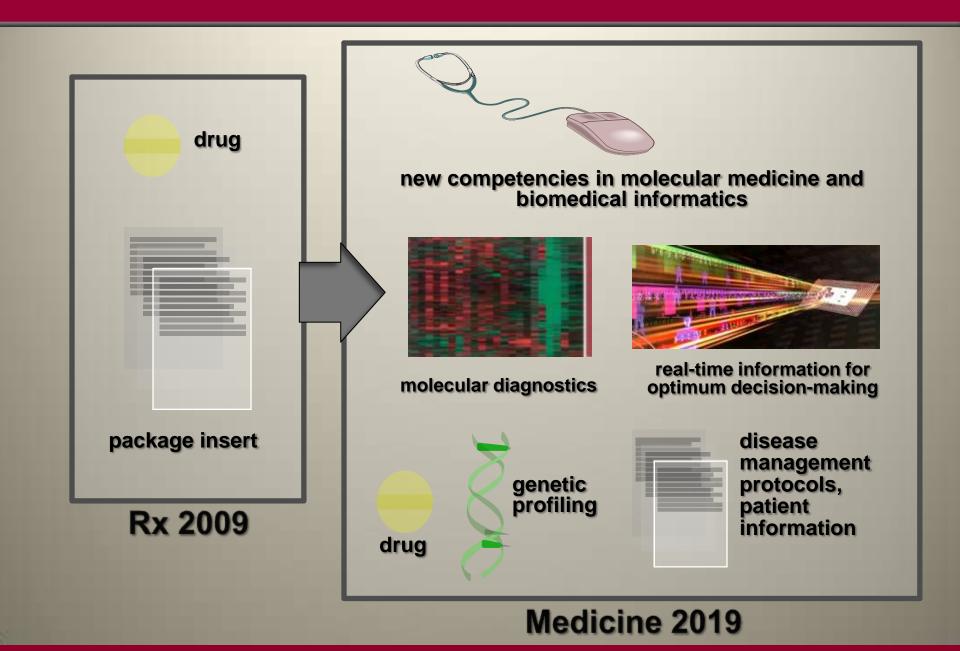
Right Rx for Right Disease

Individual Variation and AE risk



Right Rx for Right Patient

The Evolution of Molecular Medicine and Information-Based Medicine: The Foundation for Rational Care and Personalized Medicine



Adoption of New Technologies in Healthcare

- not merely innovation in technology
- parallel evolution and adoption of new business, financial and organizational models
- complexity of harmonizing incentives for diverse constituencies
- critical role of public policies in defining market entry barriers
 - regulation, reimbursement
 - professional standards and sustaining status quo
 - administrative procedures
 - governance of third party health insurance payments
- cost-based, event-/procedure-based incentives versus integrated care and disease management

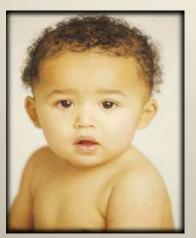
Reimbursement for Diagnostic Tests

- inadequate US Medicare coding and payment mechanisms
 - out moded, out-dated, lacking in transparency, inconsistently applied
- inappropriate assignment of existing CPT codes to new tests
- off-label use but with tangible clinical benefits
- engagement of third party payers who derive economic/clinical value from new Dx

VALUE-BASED REIMBURSEMENT
VERSUS
COST-BASED REIMBURSEMENT

Personalized Medicine: Disease Predisposition Profiling



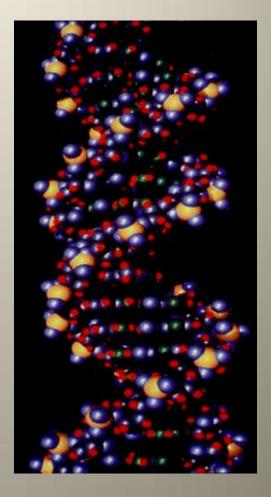












Your Genes In Context

































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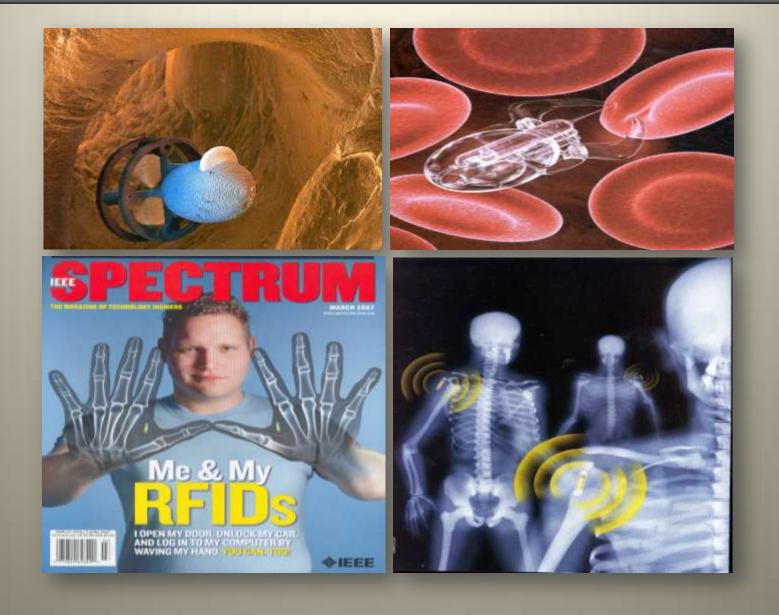
Consumer Genomics: Predisposition Risk Profiling for Late Onset, Multigenic Diseases

- unproven validity of many claimed gene-disease associations
- communication of probabilistic risk
- health literacy and consumer response to 'risk' information
- effectiveness in motivating health improvements
- role of MD and/or genetic counselors in request/interpretation of test in varied care settings
- psychological impact on future behavior and knowledge of familial implications

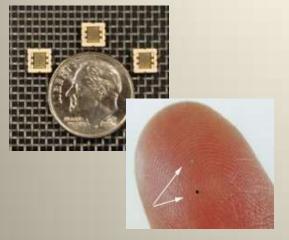
Personalized Medicine: A Broader Definition

Health Status Monitoring and the Promotion of Wellness

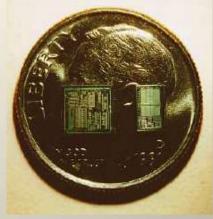
On Body: In Body Sensors/Devices For Real Time and Remote Monitoring of Individual Health Status



OBIBS and Body Area Networks (BAN's) for Remote Monitoring of Health









Microtags

In-Body Wireless Tags Sensor on a Chip

"Savings from broad-band remote monitoring for all chronically ill patients are potentially quite remarkableas much as 30 percent of all hospital, out-patient and drug expenses"

> Robert Litan **Kaufman Foundation December 2005**

cited in: Advancing Healthcare Through Broadband **Internet Innovation Alliance White Paper 2007**

On Body: In Body Sensors and Devices

Healthcare

Objective

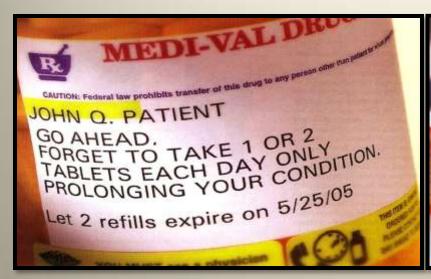
remote monitoring of health status



Applications

- multi-feature monitoring and broadband wireless networks
 - ubiquitous sensing
- enhanced autonomy for in-home aged
- proactive alerting and intervention to mitigate health incidents
- monitoring of patient compliance
- coupled linkage to remote Rx dispensing for efficient disease management

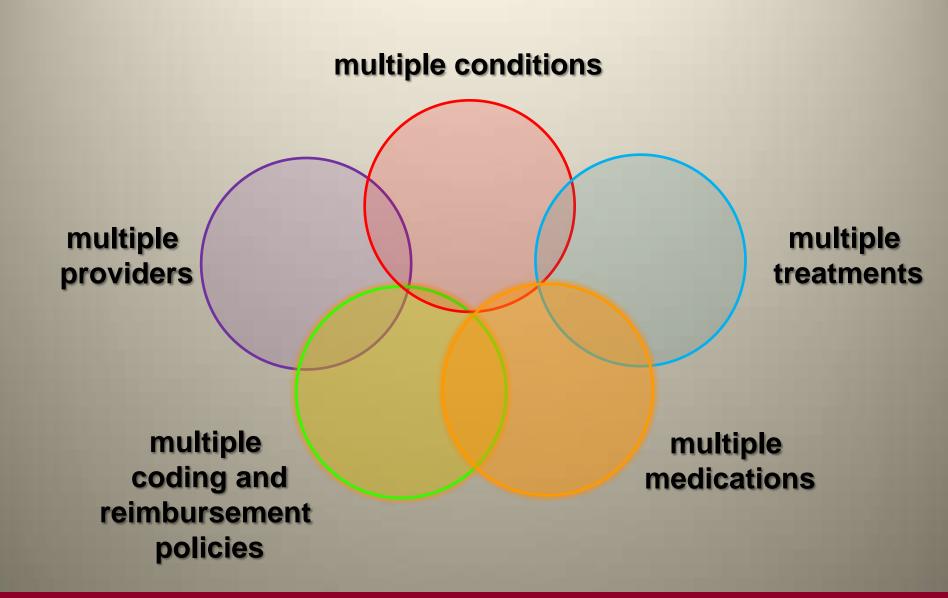
The Costs of Non-Compliance with Rx Regimens





- \$177 billion projected cost
- 20 million workdays/year lost (IHPM)
- 40% of nursing home admissions
- projected 45-75% non-compliance (WHO)
- 50-60% depressed patients (IHPM)
- 50% chronic care Rx (WHO)

Challenges in the Management of Complex Chronic Conditions and Co-Morbidities



Deloitte.

Connected Care

Technology-enabled Care at Home

Produced by the Deloitte Center for Health Solutions



State of Technology in Aging Services According to Field Experts and Thought Leaders

By:

Majd Alwan, Ph.D.,
Center for Aging Services Technologies (CAST)
American Association of Homes and Services for the Aging (AAHSA)

and

Jeremy Nobel, M.D., M.P.H, Harvard School of Public Health

Report Submitted to: Blue Shield of California Foundation

February 2008



Challenges to Moving Forward with the (Advanced) <u>Medical Home Model for Coordinated Care</u>

- lack of suitably trained PCPs
- downward trend in PCP population
- insufficient capital, incentives and facileness of HIT infrastructure
- uncertain financial rewards and savings
- inadequate reimbursement policies for preventive care
- turf wars and tensions
 - care management
 - vendors/health plans
 - reduced revenues for hospital with significant
 PCP network
 - assignment of malpractice liabilities



An Association of Independent Blue Cross and Blue Shield Plans

The Pathway to Covering America

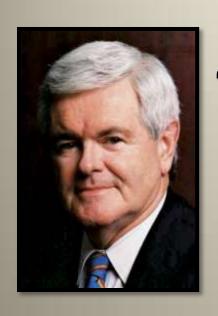


Ensuring Quality, Value and Access

Seeking 'Quality' in Healthcare



Misaligned Reimbursement Incentives: Rewarding Process Versus Results



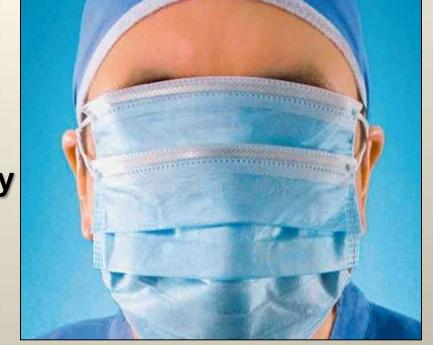
"You have a (healthcare) system that traps us into bad performance because it's the only way you can bill"

Hon. Newt Gingrich Medical Device Daily (2009) 27 Jan. p8

"If it isn't billable - it isn't going to happen!"

Knowing What Works (or Doesn't)

 Pervasive Inefficiencies and Errors in Healthcare Created by Empirical Care and Lack of Robust Outcomes and Performance Data







Knowing What Works (Or Doesn't!)

- patients have at best 50:50 chance of receiving most advisable care
- ineffective, redundant and inappropriate care
 - projected 30-50% of healthcare spending
- only 15% of clinical interventions validated by clinical trials/regulatory review
- wide geographic variations in quality and cost of care
- protracted 15 to 25 yr timeframe for adoption of best practice(s)

Evidence and Comparative Effectiveness Research (CER): The Foundation of Rational Healthcare Policy

- urgent imperative to eclipse "the archeology of clinical practice"
- limited fraction of clinical interventions validated by rigorous analysis/evidence
- benefits/risks of new technology never fully known at launch
- evaluation in clinically-relevant context(s)
- cost of CER studies
- standard-of-care and malpractice

How Much New Technology Can We Afford?

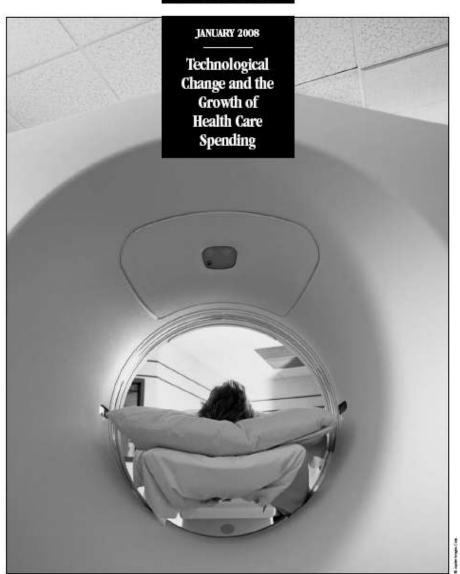








A CBO



"Half of all growth in healthcare spending in the past several decades was associated with changes in care made possible by advances in technology"

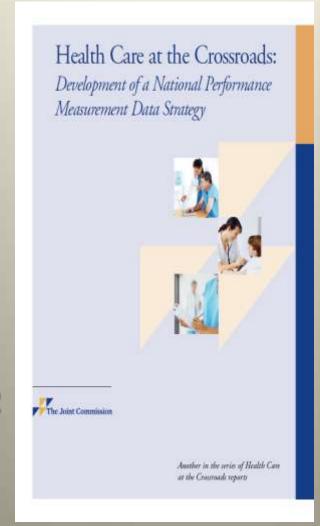
CBO January 2008

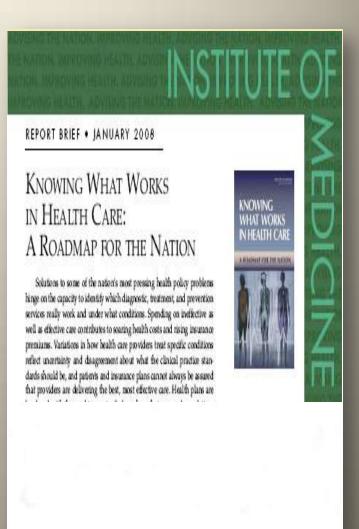
Key Questions

- what is the role of technology innovation in healthcare?
- do current public and private strategies support innovation and disruptive technologies?
- how should the 'value' of new technologies be assessed?
- how should dissemination of new valueadded technologies be supported?

The High Price of the Lack of Evidence

- \$2.3 trillion healthcare economy
- \$110 billion
 R&D
 investment
- \$0.9 billion on technology assessment
- additional \$1.2 billion in 2009 "stimulus" package





Knowing What Works: Healthcare System Performance Assessment

- allocation of incremental dollars to low-priority care as often or more frequently than high-priority care merely exacerbates current distortions
- refine analyses to focus resources where they will do the most good
- encourage optimal care via weighted measures that credit high-priority care over low-priority care
- lack of investment to devise pragmatic metrics suitable for longitudinal assessment
- new incentives for CER
- new incentives (carrots and sticks) for obligate adoption

- 2009-877
- American Recovery and Reinvestment Act (ARRA) of 2009
 - P.L. 111.5
- \$1.1 billion
 - NIH (\$400 million)
 - AHRQ (\$300 million)
 - HHS (\$400 million)
- Institute of Medicine (I0M) Report
 - 30 June 2009
 - top 100 priority projects

HHS.gov/Recovery

Federal Coordinating Council for Comparative Effectiveness Research Membership

Recovery Act Allocates \$1.1 Billion for Comparative Effectiveness Research

- superficial appeal of rational policy belies the complexity of rigorous CER
 - endpoints/outcomes
 - methodological and reporting standardization
 - stringency of patient selection/treatment regimen/compliance
 - prospective versus retrospective data
- payor engagement and impact on reimbursement policies
 - predisposition to chose lower cost intervention(s)?
 - risk of abuse and rationing of care

- superficial appeal of rational policy belies the complexity of rigorous CER
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WHO SETS PRIORITIES AND EVALUATION CRITERIA?

 predisposition to select unidimensional interventions with quantitative direct costs

versus

- complex, multidimensional interventions and assessment of direct/indirect benefits
- drugs, devices and procedures

versus

different ways of paying for care

versus

different organizational models for healthcare delivery

Demonstrating Value: Inadequate Evaluation Methods

- lack of consensus on outcome metrics and their application
- inability to integrate direct (healthcare) and indirect (socio-economic, QOL) costs
- inadequate tools to identify 'compounding' of health benefits (impact on co-morbidities)
- methodological/regulatory/reimbursement policies
 - prospective versus retrospective data
 - role of randomized clinical trials (time, cost)
 - setting guidelines and compliance monitoring
 - QALYs: national differences

"Not everything that counts can be counted, and not everything that can be counted, counts" Albert Einstein

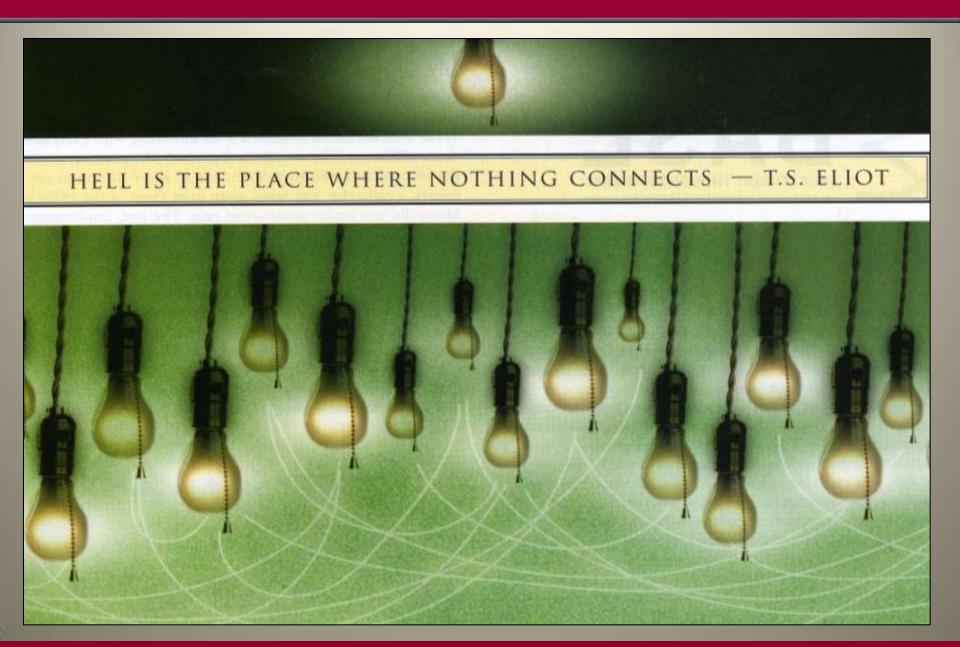


Systems-Based Approaches to Complex, Multi-Dimensional Challenges



CONNECTIVITY AND INTEGRATED CARE

Information-Based Medicine



Paper Kills!: The Inefficiencies and Risks Created by Sustained Dependence on Paper Healthcare Records



The Unacceptable Cost of Unconnected Healthcare

- extravagant waste via excessive duplication of tests/procedures
- error via lack of crucial data
- lack of data capture for outcomes analysis and individual physician performance
- failure to capture population-based disease parameters
 - sentinel public health/national security
 - meta-analysis of outcomes
 - drug and device safety and recall

CONSUMERS

Consumer Directed Healthcare Plans

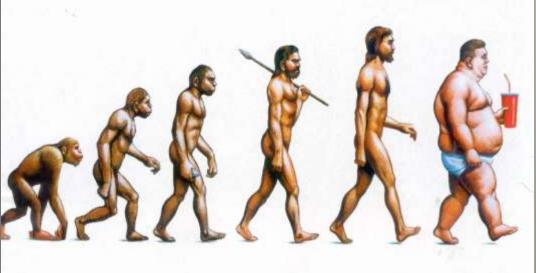
"Until the person receiving the product is responsible in some fashion for the costs, there will be no incentive to spend responsibly"

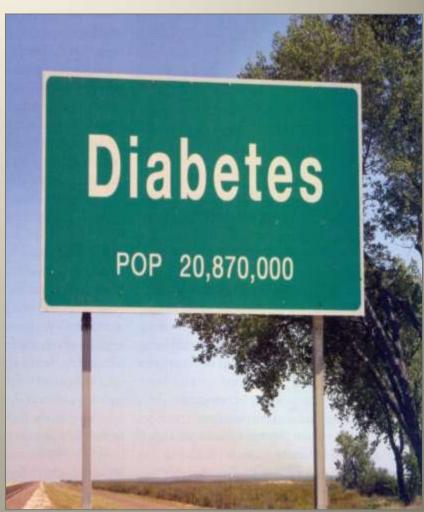
Scott Serota
CEO, BCBS Association of Chicago
Chief Executive Magazine, March 2007 p. 50

After a Short Stay in America, Michelangelo's David Returned to Europe

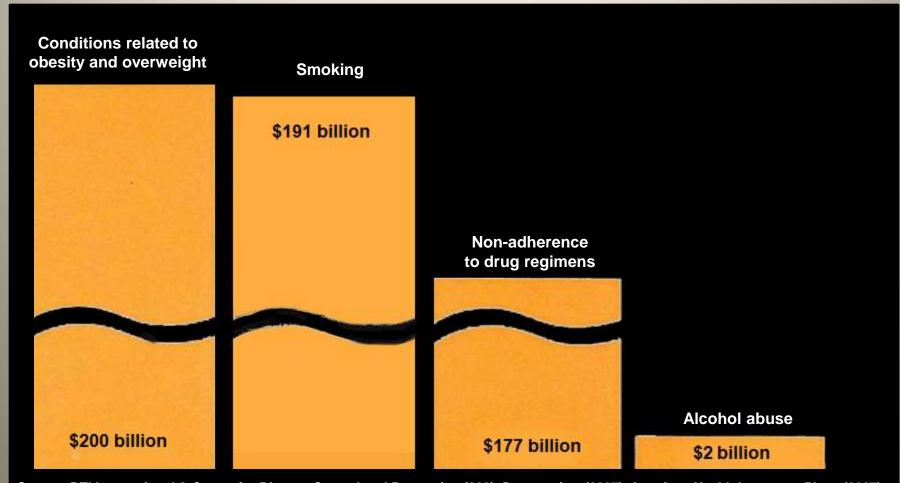


The shape of things to come





Annual Excess Healthcare Costs Related to Consumer Behavior



Source: RTI International & Center for Disease Control and Prevention (200), Datamonitor (2007), Americas Health Insurance Plans (2007), Commonwealth Fund (2007), Agency for Health Research and Quality (2003), Analysis by PricewaterhouseCoopers' Health Research

The Case for Wellness

- 30-60% of health plan claims are related to health risks that are modifiable by nutrition, exercise, stress reduction, etc.
- well-managed employer health and productivity management programs return \$6-15 for every dollar spent
- cost of smoking: healthcare cost of smoking over a lifetime = \$220K per person = \$40 in healthcare cost per pack of cigarettes smoked!
- 67% of the US population is overweight or obese, and 22% of current healthcare costs are obesityrelated

Source: Wellness Councils of America



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Personalized Medicine: Consumer-Centric Healthcare: A Key Driver

- cost-shifting to consumers
- clinical and economic benefits of coordinated care of complex chronic conditions
- lifestyle and disease risk mitigation
- cost-driven transitions from 'passive patient' to 'engaged consumer'
- new information intermediaries

Telecommunications and Media Industry Convergence: Implications for Healthcare

The Infocosm: Emerging Networks of Global Connectivity





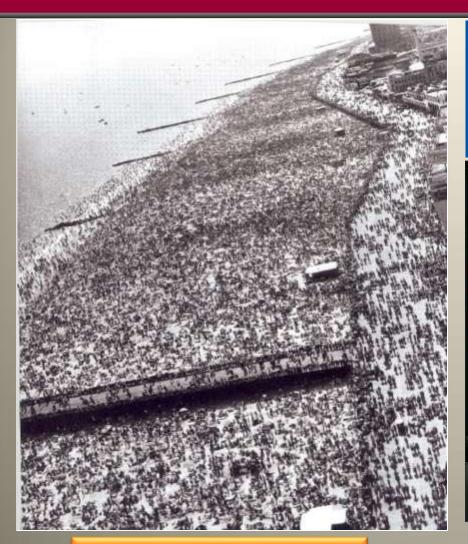








The Changing Nature of Social Interaction



facebook







Herd Behavior: 1951

1.3 Million Bathers, Coney Island, NY **Herd Behavior: 2009**

Social Networks and Virtual Communities

Consumer-Directed Healthcare: The Wellness Premium

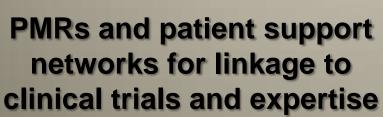
- leveraging social and peer networks
- increased role of fitness industry and entertainment in healthcare
 - "success via distraction"
- "virtual touch"
 - web-based consultation and diagnostic algorithms
 - emerging generational gap in need for direct physical interaction with physician
- evolution of 'near-patient' health status profiling
 - POC and in-home Dx
 - OBIBs

The Great Network Inflection Point

- multi-billion user internet
- AORTA (always on, real time, access)
- connectivity via low cost, portable, multi-function devices
 - "universal connection devices"
- every piece of information will have geographic and time coordinates
- ubiquitous access plus customized profiling creates a world shaped by individual choices

Connecting Patients (and Consumers) to Optimum Healthcare Resources







integrated care of chronic conditions and specialty Rx distribution

In-Home Health Connection: Engaging the Elderly



The Dominant Future Element in Primary Healthcare Delivery???







Save money. Live better. ~









Healthcare Information and Privacy

· 2010: 15 Petabits (1016) / \$250,000

Human Genome: 10 Gigabits (10¹¹)

For a few million dollars, one could store the complete genome of every American and European

...for several more, could add credit card records, telephone logs, travel history,...





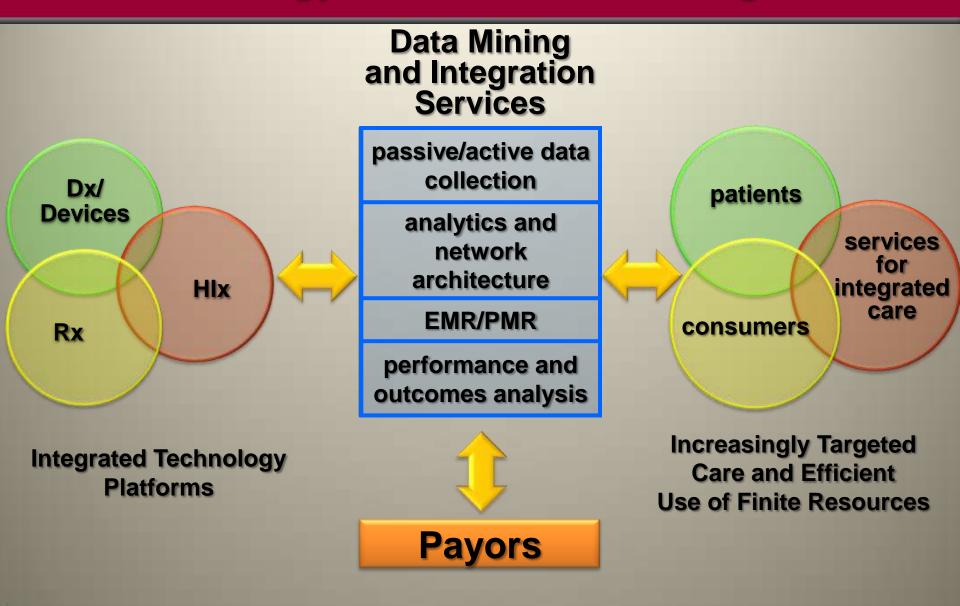
When Will Interoperable Electronic Medical Records Become a Reality?

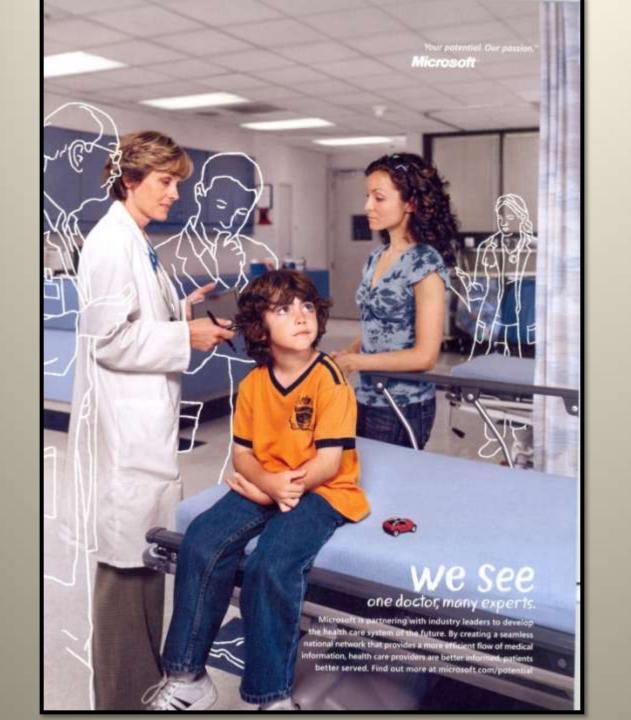


American Recovery and Reinvestment Act (ARRA) 2009

- \$19 billion for healthcare IT
- Medicare payment up to \$44K for physician with qualifying EHRs (2011)
- Medicare reductions for physicians/hospitals that lack qualifying HER by 2014
- CPOE by 2011 to qualify for Medicare incentive payments
- HITECH: separate new law embedded in ARRA
 - Health Information Technology for Economic and Clinical Health (HITECH) Act
 - policies/standards for national Hlx network

A New Healthcare Ecosystem Arising From Technology and Market Convergence





Creating a New Network of Connected Expertise to Accelerate Innovation in Healthcare Delivery

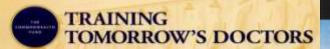
- ever faster generation of new information
- diversification of innovation sources
- current healthcare ecosystem is too fragmented to fully leverage novel content and shared learning
- global sourcing
- rise of new business models of 'expertise networks' that eclipse current monolithic single company innovation models

From Ambiguity to Certainty: Competitive Superiority via Analysis of a Burgeoning Infocosm

- new intermediaries for analysis/packaging of healthcare data
- global sourcing of data and expertise
- lower transactional costs
- higher efficiency in use of expensive, finite resources
- increasingly predictable cost structure and predictable performance of products and procedures
- improved clinical and economic outcomes

Healthcare Reform: Identification of New Value Drivers

- precision diagnostics: the most powerful driver of rational care decisions
- structural shift in healthcare delivery from encounter-/procedure-driven to incentives for integrated disease management
- clinical and economic benefits of coordinated care of complex chronic conditions
- cost-shifting to consumers
- lifestyle and disease risk mitigation
- real-time health information and individual health status tracking
- cost-driven transitions from 'passive patient' to 'engaged consumer'



The Medical Education Mission of Academic Health Centers

A Report of The Commonwealth Fund Task Force on Academic Health Centers

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BUILDING A SAFER HEALTH SYSTEM

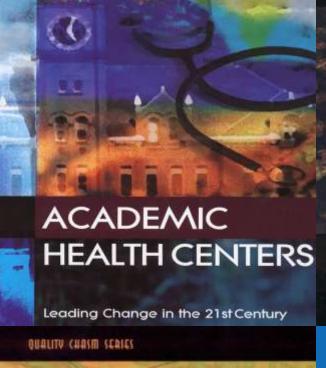
August 2004

ACGME Bulletin

Accreditation Council for Graduate Medical Education

EDITOR'S INTRODUCTION

Graduate Medical Education and Patient Safety



INSTITUTE OF MEDICINE



A BRIDGE TO QUALITY

INSTITUTE OF MEDICINE

A New Health System for the 21st Century



High Quality Medical Care

Report of the Ad Hoc. Committee of Deans



July 2004

Commissioned for the AAMC Institute for Improving Medical Education

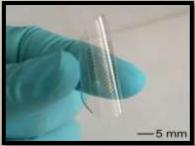
The Urgent Need for Reform of the Medical Education Curriculum

molecular medicine



information-based medicine







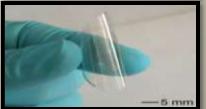
The Urgent Need for Reform of the Medical Education Curriculum

molecular medicine

engineering-based medicine

- information-based medicine
- recalibration of the role of the MD in healthcare delivery
 - from 'art' to 'science'
 - from individual artisan to integrated team player









The Coming Convergence in Healthcare Delivery

Technologies

biotechnology, medicine, engineering, computing

Clinical Practice

- molecular medicine and increasingly customized care
- diagnostic, drug and device combinations
- POC testing and remote monitoring
- reduced error and improved compliance
- improved clinical and economic outcomes

Realigned Incentives

- integrated care for complex chronic diseases
- earlier disease detection and risk reduction
- wellness versus illness
- health status monitoring

The Coming Convergence in Healthcare Delivery

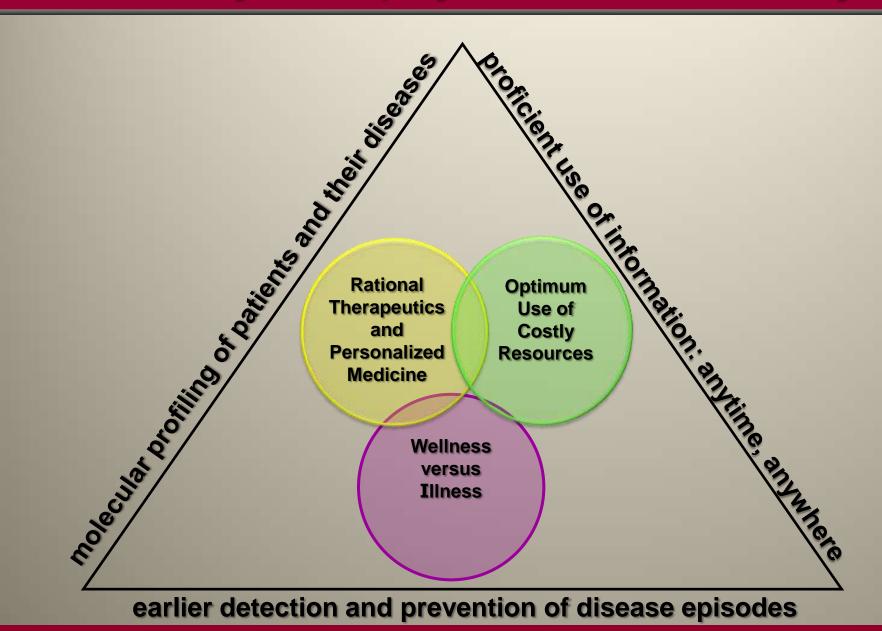
Consumers

- increased personal responsibility for health
- new incentives for wellness/compliance
- health status monitoring

Connectivity

- integrated care networks for chronic disease
- improved outcomes and effectiveness
- social networks and informed consumers
- new supplier networks of specialized turnkey expertise
- value added 'content' services for clinical data mining

The Urgent Imperative for New Drivers of Efficiency and Equity in Healthcare Delivery



Building an Integrated Framework for Personalized Medicine

